designee in the manner and timeframe specified by HHS.

(2) An issuer must ensure that it and its initial validation auditor comply with the security standards described at 45 CFR 164.308, 164.310, and 164.312 in connection with the initial validation audit, the second validation audit, and any appeal.

[78 FR 15531, Mar. 11, 2013, as amended at 79 FR 13836, Mar. 11, 2014]

Subpart H—Distributed Data Collection for HHS-Operated Programs

SOURCE: 78 FR 15531, Mar. 11, 2013, unless otherwise noted.

§ 153.700 Distributed data environment.

(a) *Dedicated distributed data environments.* For each benefit year in which HHS operates the risk adjustment or reinsurance program on behalf of a State, an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in the State, as applicable, must establish a dedicated data environment and provide data access to HHS, in a manner and timeframe specified by HHS, for any HHS-operated risk adjustment and reinsurance program.

(b) *Timeline.* An issuer must establish the dedicated data environment (and confirm proper establishment through successfully testing the environment to conform with applicable HHS standards for such testing) three months prior to the first date of full operation.

§ 153.710 Data requirements.

(a) *Enrollment, claims, and encounter data.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must provide to HHS, through the dedicated data environment, access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by HHS.

(b) *Claims data.* All claims data submitted by an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must have resulted in payment by the issuer (or payment of cost sharing by the enrollee).

(c) *Claims data from capitated plans.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, that does not generate individual enrollee claims in the normal course of business must derive the costs of all applicable provider encounters using its principal internal methodology for pricing those encounters. If the issuer does not have such a methodology, or has an incomplete methodology, it must supplement the methodology in a manner that yields derived claims that are reasonable in light of the specific service and insurance market that the plan is serving.

(d) *Interim dedicated distributed data environment reports.* Within 30 calendar days of the date of an interim dedicated distributed data environment report from HHS, the issuer must, in a format specified by HHS, either:

(1) Confirm to HHS that the information in the interim report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with §153.700(a) for the timeframe specified in the report; or

(2) Describe to HHS any discrepancy it identifies in the interim dedicated distributed data environment report.

(e) *Final dedicated distributed data environment report.* Within 15 calendar days of the date of the final dedicated distributed data environment report from HHS, the issuer must, in a format specified by HHS, either:

(1) Confirm to HHS that the information in the final report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with §153.700(a) for the benefit year specified in the report; or

(2) Describe to HHS any discrepancy it identifies in the final dedicated distributed data environment report.

(f) *Unresolved discrepancies.* If a discrepancy first identified in an interim

or final dedicated distributed data environment report in accordance with paragraphs (d)(2) or (e)(2) of this section remains unresolved after the issuance of the notification of risk adjustment payments and charges or reinsurance payments under §153.310(e) or §153.240(b)(1)(ii), respectively, an issuer of a risk adjustment covered plan or reinsurance-eligible plan may make a request for reconsideration regarding such discrepancy under the process set forth in §156.1220(a) of this subchapter.

(g) *Risk corridors and MLR reporting.* (1) Notwithstanding any discrepancy report made under paragraph (d)(2) or (e)(2) of this section, or any request for reconsideration under §156.1220(a) of this subchapter with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees; reinsurance payment; cost-sharing reconciliation payment or charge; or risk corridors payment or charge, unless the dispute has been resolved, an issuer must report, for purposes of the risk corridors and MLR programs:

(i) The risk adjustment payment to be made or charge assessed, including an assessment of risk adjustment user fees, by HHS in the notification provided under §153.310(e);

(ii) The reinsurance payment to be made by HHS in the notification provided under §153.240(b)(1)(ii);

(iii) A cost-sharing reduction amount equal to the amount of the advance payments of cost-sharing reductions paid to the issuer by HHS for the benefit year; and

(iv) For medical loss ratio report only, the risk corridors payment to be made or charge assessed by HHS as reflected in the notification provided under §153.510(d).

(2) An issuer must report any adjustment made following any discrepancy report made under paragraph (d)(2) or (e)(2) of this section, or any request for reconsideration under §156.1220(a) of this subchapter with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees; reinsurance payment; cost-sharing reconciliation payment or charge; or risk corridors payment or charge; or following any audit, where such adjustment has not be accounted for in a prior risk corridors or medical loss ratio report, in the next following risk corridors or medical loss ratio report.

[78 FR 15531, Mar. 11, 2013, as amended at 79 FR 13837, Mar. 11, 2014]

§153.720 Establishment and usage of masked enrollee identification numbers.

(a) *Enrollee identification numbers.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must—

(1) Establish a unique masked enrollee identification number for each enrollee; and

(2) Maintain the same masked enrollee identification number for an enrollee across enrollments or plans within the issuer, within the State, during a benefit year.

(b) *Prohibition on personally identifiable information.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program on behalf of the State, as applicable, may not—

(1) Include enrollee's personally identifiable information in the masked enrollee identification number; or

(2) Use the same masked enrollee identification number for different enrollees enrolled with the issuer.

§153.730 Deadline for submission of data.

A risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must submit data to be considered for risk adjustment payments and charges and reinsurance payments for the applicable benefit year by April 30 of the year following the applicable benefit year.

§153.740 Failure to comply with HHS-operated risk adjustment and reinsurance data requirements.

(a) *Enforcement actions.* If an issuer of a risk adjustment covered plan or reinsurance-eligible plan fails to establish